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COMMITTEE OF EXPERTS ON THE TRANSPORT
OF DANGEROUS GOODS

REPORT OF THE COMMITTEE OF EXPERTS ON ITS SEVENTEENTH SESSION

(7-16 December 1992)

Addendum 5

Annex 6: Revised text for Division 6.2 in Chapter 6 of the Recommendations on the Transport of Dangerous Goods.

Note: This text replaces paragraphs 6.9 to 6.18 of Chapter 6 of the seventh revised edition of the Recommendations on the Transport of Dangerous Goods (ST/SG/AC.10/1/Rev.7)

GE.93-20338

DIVISION 6.2 - INFECTIOUS SUBSTANCES

6.9 Definitions

(a) 'Infectious substances' are those substances containing viable micro-organisms, including a bacterium, virus, rickettsia, parasite, fungus, or a recombinant, hybrid or mutant, that are known or reasonably believed to cause disease in animals or humans. However, they are not subject to the recommendations for this division if the spread of disease to humans or animals exposed to such substances is considered unlikely.

NOTE: Infectious substances should be considered for classification in Division 6.2 and for assignment to UN 2814 or UN 2900 after allocation to four risk groups*/ based on criteria developed by the World Health Organization (WHO). The criteria according to the level of risk of infection are as follows:

(i) in risk group IV (high individual risk, high community risk) are micro-organisms that cause severe human or animal disease, may present a high risk of spreading and there is usually no effective prophylaxis or treatment available;

(ii) in risk group III (high individual risk, low community risk) are micro-organisms that cause severe human or animal disease, may present a high risk of spreading, but there is usually effective prophylaxis or treatment available;

(iii) in risk group II (moderate individual risk, limited community risk) are micro-organisms that cause human or animal disease, are unlikely to spread, and there is usually effective prophylaxis or treatment available;

(iv) in risk group I (low individual and community risk) are micro-organisms that are unlikely to cause human or animal disease and they can be disregarded in these Recommendations.

(b) "Genetically modified micro-organisms and organisms" are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. They are divided into the following categories:

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*/ Further explanations of these risk groups can be found in the "Laboratory Biosafety Manual, 1983" published by the World Health Organization (WHO). They should not be confused with "Packing Groups" as used in these Recommendations.

(i) genetically modified micro-organisms which meet the definition of an infectious substance given above should be classified in Division 6.2 and assigned to UN 2814 or to UN 2900;

(ii) genetically modified organisms, which are known or suspected to be dangerous to humans, animals or the environment, should be transported in accordance with conditions specified by the competent authorities;

(iii) animals which contain or are contaminated with genetically modified micro-organisms and organisms that meet the definition of an infectious substance should be transported in accordance with conditions specified by the competent authorities;

(iv) except when authorized for unconditional use by the Governments of the countries of origin, transit and destination, genetically modified micro-organisms which do not meet the definition of infectious substances but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction should be classified in Class 9 and assigned to UN 3245.

(c) 'Biological products' are either finished biological products for human or veterinary use manufactured in accordance with the requirements of national public health authorities and moving, if required, under special approval or licence from such authorities; or biological products transported prior to licensing for development or investigation purposes or finished products for experimental treatment of humans or animals and which are manufactured in compliance with the requirements of national public health authorities. They also cover unfinished biological products prepared in accordance with procedures of specialized government agencies.

NOTE: Some licensed vaccines may present a biohazard in certain parts of the world only. In that case competent authorities may require these vaccines to comply with the requirements for infectious substances or may impose other restrictions.

(d) 'Diagnostic specimens' are any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids being transported for diagnostic or investigation purposes, but excluding live infected animals.

(e) For the purposes of these Recommendations, biological products and diagnostic specimens are divided into the following groups:

(i) those known or thought likely to contain infectious substances; diagnostic specimens transported to undergo confirmatory testing should be considered to fall within this group;

(ii) those where a relatively low probability exists that infectious substances are present. For example, diagnostic specimens being transported to undergo routine screening tests or for the purpose of initial diagnosis should be considered to fall within this group;

(iii) those known not to contain infectious substances.

(f) Wastes transported under UN 3291 are wastes derived from the medical treatment of animals or humans or from bio-research where there is a relatively low probability that infectious substances are present. Waste infectious substances which can be specified should be assigned to UN 2814 or to UN 2900. Decontaminated wastes which previously contained infectious substances should be considered non-dangerous unless the criteria of another class are met.

6.10 Biological products and diagnostic specimens

6.10.1 Biological products known to contain, or thought likely to contain, any infectious substances should meet all the requirements for infectious substances. Biological products referred to in 6.9 (e) (ii) should meet all the provisions for infectious substances except when the following conditions are met:

(a) the primary receptacle(s) do not contain more than 50 ml;

(b) the outer packaging does not contain more than 50 ml when fragile primary receptacles are used or 100 ml when other than fragile primary receptacles are used;

(c) the primary receptacle(s) are leakproof; and

(d) the packaging is in accordance with 6.13.

6.10.2 Diagnostic specimens known to contain, or thought likely to contain, any infectious substances should meet all the requirements for infectious substances. Diagnostic specimens referred to in 6.9 (e) (ii) should meet all the provisions for infectious substances except when the following conditions are met:

(a) the primary receptacle(s) do not contain more than 100 ml;

(b) the outer packaging does not contain more than 500 ml;

(c) the primary receptacle(s) are leakproof; and

(d) the packaging is in accordance with 6.13.

Responsibility of consignor of infectious substances

6.11 The transport of infectious substances requires co-ordinated action by the consignor, the carrier and the consignee to ensure safety and arrival on time and in proper condition. To this end, the measures recommended below should be taken.

(a) Advance arrangements between consignor, carrier and consignee:

Dispatch of infectious substances should not take place before advance arrangements have been made between consignor, carrier and consignee or before the consignee has confirmed with his competent authorities that the substances can legally be imported and that no delay will be incurred in the delivery of the consignment to its destination.

(b) Preparation of dispatch documents:

In order to secure transmission without hindrance it is necessary to prepare all dispatch documents, including the transport document (see Chapter 13, section 13.6), in strict accordance with rules governing the acceptance of the goods to be dispatched. If the substance is perishable, warnings should appear on the transport document, for instance: "Keep cool, between + 2°C and + 4°C" or "Keep frozen" or "Do not freeze". The full address of the consignee should be shown on the appropriate dispatch document, together with the name of a responsible person and his telephone number.

(c) Routeing:

Whatever the mode used, transport should be by the quickest possible routeing. If transshipment is necessary, precautions should be taken to ensure special care, expeditious handling and monitoring of the substances in transit. Transport documents should show the number of the flight or train, its date and the name(s) of the airport(s) or station(s) of transshipment.

(d) Timely notification of all transport data by consignor to consignee:

The consignor should notify the consignee in advance of transport details, such as: means of transport, flight or train number(s), transport document number and date and hour of expected arrival at the point of destination, so that the consignment can be collected promptly. The most rapid means of communication should be used for this notification.

General packing requirements and communication of information

6.12 Consignors of infectious substances should ensure that packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during transport.

6.12.1 The packaging should, as demonstrated by tests, be capable of successfully passing the design type tests detailed in 6.14.

6.12.2 The terms and definitions of 9.2 and the general packing requirements of 9.3 (except 9.3.3, 9.3.9 to 9.3.12 and 9.3.15) are applicable to the packing of infectious substances.

6.12.3 Information should be provided, as follows:

(a) inside the package: an itemized list of contents should be enclosed between the secondary packaging and the outer packaging; and

(b) outside the package: primary label No. 6.2 (see 13.5.1) should be affixed to the outer packaging, together with any other label or marking required by the nature of the contents.

6.12.4 Before an empty packaging is returned to the consignor, or sent elsewhere, it should be thoroughly disinfected or sterilized and any label or marking indicating that it had contained an infectious substance should be removed or obliterated.

Packing requirements

6.13 A packaging should include the following essential elements:

(a) An inner packaging comprising:

(i) watertight primary receptacle(s);

(ii) a watertight secondary packaging;

(iii) absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if several primary receptacles are placed in a single secondary packaging, they should be individually wrapped so as to prevent contact between them.

(b) An outer packaging of adequate strength for its capacity, mass and intended use, and with a minimum external dimension of 100 mm.

6.13.1 Inner packagings containing infectious substances should not be consolidated with inner packagings containing other types of goods.

6.13.2 Other than for exceptional consignments, e.g. whole organs which require special packaging, infectious substances should be packed in accordance with the following recommendations.

(a) Lyophilized substances

Primary receptacles should include flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.

(b) Liquid or solid substances

(i) For substances consigned at ambient temperature or at a higher temperature, primary receptacles should be of glass, metal or plastics. Positive means of ensuring a leakproof seal should be provided, e.g. a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they should be reinforced with adhesive tape.

(ii) For substances consigned refrigerated or frozen, ice or dry ice should be placed around the secondary packaging(s). Interior supports should be provided to secure secondary packaging(s) in position after the ice or dry ice has dissipated. If ice is used, the outer packaging should be leakproof. If dry ice is used, the outer packaging should permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging should maintain their integrity at the temperature of the refrigerant used.

(iii) For substances consigned in liquid nitrogen, plastics primary receptacles capable of withstanding very low temperature should be used. The secondary packaging should also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacle individually. Requirements for the consignment of liquid nitrogen should also be fulfilled. The primary receptacle and the secondary packaging should maintain their integrity at the temperature of the liquid nitrogen.

6.13.3 Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging should be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range -40°C to +55°C.

6.13.4 Unless an infectious substance cannot be consigned by any other means, live vertebrate or invertebrate animals should not be used to consign such a substance. Infected animals should be consigned in accordance with conditions specified by the competent authority.

6.13.5 A packaging that meets the requirements of this section and of 6.14 may, after decision by the competent authority, be marked with:

(a) the United Nations packaging symbol;

(b) the text CLASS 6.2;

(c) the last two digits of the year of manufacture of the packaging;

(d) the state authorizing the allocation of the mark, indicated by the distinguishing sign for motor vehicles in international traffic;

(e) the name of the manufacturer or other identification of the packaging specified by the competent authority.

6.13.6 Examples of marking:

CLASS 6.2/92	as in 6.13.5 (a), (b), (c)
S/SP-9989-ERIKSSON	as in 6.13.5 (d), (e)

16.14 Test requirements for packagings

6.14.1 Other than for packagings for live animals and organisms, samples of each packaging should be prepared for testing as described in 6.14.2 and then subjected to the tests in 6.14.3 to 6.14.5. If the nature of the packaging makes it necessary, equivalent preparation and tests are permitted, provided that these may be demonstrated to be at least as effective.

6.14.2 Samples of each packaging should be prepared as for transport except that a liquid or solid infectious substance should be replaced by water or, where conditioning at -18°C is specified, by water/antifreeze. Each primary receptacle should be filled to 98 % capacity.

6.14.3 Packagings prepared as for transport should be subjected to the tests in Table 6.2, which - for test purposes - categorizes packagings according to their material characteristics. For outer packagings, the headings in the table relate to fibreboard or similar materials whose performance may be rapidly affected by moisture; plastics which may embrittle at low temperature; and other materials such as metal whose performance is not affected by moisture or temperature. If a primary receptacle and a secondary packaging of an inner packaging are made of different materials, the material of the primary receptacle determines the appropriate test. In instances where a primary receptacle is made of two materials, the material most liable to damage should determine the appropriate test.

Table 6.2: TESTS REQUIRED

Material of					Tests required				
outer packaging			inner packaging		Refer to 6.14.4				Refer to 6.14.5
Fibre-board	Plastics	Other	Plastics	Other	(a)	(b)	(c)	(d)	
x			x			x	x	when	x
x				x		x		dry	x
	x		x				x	ice is	x
	x			x			x	used	x
		x	x				x		x
		x		x	x				x

6.14.4 (a) Samples should be subjected to free-fall drops on to a rigid, non-resilient, flat, horizontal surface from a height of 9 m. Where the samples are in the shape of a box, five should be dropped in sequence:

flat on to the base,

flat on to the top,

flat on to the longest side,

flat on to the shortest side,

on to a corner.

Where the samples are in the shape of a drum, three should be dropped in sequence:

diagonally on to the top chime, with the centre of gravity directly above the point of impact,

diagonally on to the base chime,

flat on to the side.

Following the appropriate drop sequence, there should be no leakage from the primary receptacle(s) which should remain protected by absorbent material in the secondary packaging.

(Note: While the sample should be released in the required orientation, it is accepted that for aerodynamic reasons the impact may not take place in that orientation.)

(b) The sample should be fully immersed in water for a period of at least 5 minutes and then allowed to drain for not more than 30 minutes at 23 °C and 50 ± 2 % relative humidity. It should then be subjected to the test described in (a).

(c) The sample should be conditioned in an atmosphere of -18 °C or less for a period of at least 24 hours and within 15 minutes of removal from that atmosphere be subjected to the test described in (a). Where the sample contains dry ice, the conditioning period may be reduced to 4 hours.

(d) Where the packaging is intended to contain dry ice, a test additional to that specified in (a) or (b) or (c) should be carried out. One sample should be stored so that all the dry ice dissipates and then be subjected to the test described in (a).

6.14.5 Packagings with a gross mass of 7 kg or less should be subjected to the tests described in (a) below and packagings with a gross mass exceeding 7 kg to the tests in (b) below.

(a) Samples should be placed on a level hard surface. A cylindrical steel rod with a mass of at least 7 kg, a diameter not exceeding 38 mm and the impact end edges a radius not exceeding 6 mm, should be dropped in a vertical free fall from a height of 1 m, measured from the impact end to the impact surface of the sample. One sample should be placed on its base. A second sample should be placed in an orientation perpendicular to that used for the first. In each instance the steel rod should be aimed to impact the primary receptacle. Following each impact, penetration of the secondary packaging is acceptable, provided that there is no leakage from the primary receptacle(s).

(b) Samples should be dropped on to the end of a cylindrical steel rod. The rod should be set vertically in a level hard surface. It should have a diameter of 38 mm and the edges of the upper end a radius not exceeding 6 mm. The rod should protrude from the surface a distance at least equal to that between the primary receptacle(s) and the outer surface of the outer packaging with a minimum of 200 mm. One sample should be dropped in a vertical free fall from a height of 1 m, measured from the top of the steel rod. A second sample should be dropped from the same height in an orientation perpendicular to that used for the first. In each instance the packaging should be so orientated that the steel rod would penetrate the primary receptacle(s). Following each impact, penetration of the secondary packaging is acceptable, provided that there is no leakage from the primary receptacle(s).

6.14.6 Provided an equivalent level of performance is maintained, the following variations in the primary receptacles placed within an intermediate packaging are allowed without further testing of the completed package:

(a) Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided:

(i) the primary receptacles are of similar design to the tested primary receptacle (e.g. shape: round, rectangular, etc.);

(ii) the material of construction of the primary receptacle (glass, plastics, metal, etc.) offers resistance to impact and stacking forces equal to or greater than that of the originally tested primary receptacle;

(iii) the primary receptacles have the same or smaller openings and the closure is of similar design (e.g. screw cap, friction lid, etc.);

(iv) sufficient additional cushioning material is used to take up void spaces and to prevent significant movement of the primary receptacles; and

(v) primary receptacles are oriented within the intermediate packaging in the same manner as in the tested package.

(b) A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in (a) above, may be used provided sufficient cushioning is added to fill the void space(s) and to prevent significant movement of the primary receptacles.

6.14.7 Waste clinical or (bio) medical substances should meet all the requirements for infectious substances except the packaging requirements of 6.13 and of this section. Such waste should be carried in rigid packagings or IBCs in accordance with the provisions of chapters 9 or 16 for solids, at the Packing Group II performance level, provided there is less than 20 ml of liquid in any one receptacle, the total amount of liquid is less than 10% of the package volume and the packagings are capable of retaining liquids. Packages containing larger quantities of liquid should be carried in rigid packagings or IBCs in accordance with the provisions of chapters 9 or 16 at the Packing Group II performance level for liquids. Packagings or IBCs intended to contain sharp objects such as broken glass and needles should be resistant to puncture and retain liquids under the performance test conditions in chapters 9 or 16.

Responsibility of carrier

6.15 Carriers and their staff should fully understand all applicable regulations for the packing, labelling, transport and documentation of consignments of infectious substances. The carrier should accept and expedite the transport of consignments conforming to the rules in force. If the carrier finds any error in the labelling or documentation, he should immediately notify the consignor or consignee so that the appropriate corrective measures may be taken.

Responsibility of consignee

6.16 The consignee should obtain from the competent authorities the necessary licence for the import of infectious substances. The consignee should also provide the consignor with any import licences, authorizations or other documents required by the competent authorities. Upon receipt of known or suspected high-risk infectious substances of human or animal origin, the consignee should immediately acknowledge receipt to the consignor by the most rapid means of communication available to him.

6.16.1 The consignee should have a suitably equipped and adequately staffed receiving area. All incoming consignments of infectious substances should be unpacked in areas designated for this purpose and under conditions of containment commensurate with the degree of danger presented by the infectious substances. A record should be kept of the receipt of all substances.

Action to be taken in the event of damage or leakage

6.17 If any person responsible for the carriage or opening of packages containing infectious substances becomes aware of damage to or leakage from such packages, he should:

(a) avoid handling the package or keep handling to a minimum;

(b) inspect adjacent packages for contamination and put aside any that may have been contaminated;

(c) inform the appropriate public health authority or veterinary authority, and provide information on any other countries of transit where persons may have been exposed to danger; and

(d) notify the consignor and/or the consignee.

International notification

6.18 A public health or veterinary authority to which actual or suspected leakage from or damage to a package is reported should notify the authorities of any countries in which the package may have been handled, including countries of transit.